COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02-VI-2005
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NOT FOR PUBLICATION

COMMISSION DECISION

of 02-VI-2005

on the renewal of the marketing authorisation for the medicinal product for human use "Azopt - Brinzolamide", granted by Decision C(2000)576

(Text with EEA relevance)

ONLY THE ENGLISH TEXT IS AUTHENTIC

COMMISSION DECISION

of 02-VI-2005

on the renewal of the marketing authorisation for the medicinal product for human use "Azopt - Brinzolamide", granted by Decision C(2000)576

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Alcon Laboratories (UK) Ltd., on 28 October 2004, under Article 13(1) of Regulation (EEC) No 2309/93 with a view to the renewal of the marketing authorisation for the medicinal product "Azopt - Brinzolamide"

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2], and in particular Article 61(3) thereof,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 17 February 2005,

Whereas:

(1) Following consideration by the Agency of a dossier containing up-to-date information on pharmacovigilance, it appears that the medicinal product "Azopt - Brinzolamide" entered in the Community register of medicinal products under Nos EU/1/00/129/001-003 and authorised by Commission Decision C(2000)576 of 9 March 2000, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

[1] OJ L 214, 24.8.1993, p. 1 Regulation as last amended by [Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19)].

[2] OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).]

[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34)].

(2) The marketing authorisation which expires on 10 March 2005 should therefore be renewed.

(3) During the same period, Alcon Laboratories (UK) Ltd. submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet. The competent authority did not oppose the proposed change within the 90-day time-limit.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2000)576 of 9 March 2000 which expires on 10 March 2005 is renewed.

Article 2

Decision C(2000)576 is amended as follows:

1) The list of notifications for changes to an aspect of the labelling or the package leaflet, accepted between 13 May 2004 and 17 February 2005, is added to the updated marketing authorisation;

Application number Annex (EU numbers affected)

EMEA/H/C/267/N/08 IIIAB (EU/1/00/129/001-003)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

The period of validity of the renewed authorization shall be five years from 10 March 2005.

Article 4

This Decision is addressed to Alcon Laboratories (UK) Ltd., Pentagon Park, Boundary Way, Hemel Hempstead, Herts HP2 7UK, United Kingdom.

Done at Brussels, 02-VI-2005

For the Commission
Günter VERHEUGEN
Member of the Commission